

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE:)	
PHARMASTEM THERAPEUTICS, INC.,)	MDL Docket No. 05-md-1660-GMS
PATENT LITIGATION)	ALL CASES
)	
)	
)	

PHARMASTEM'S INITIAL PRETRIAL CONFERENCE BRIEF

Pursuant to Section 20 of this Court's Practice and Procedure Order dated July 19, 2005, PharmaStem Therapeutics, Inc. ("PharmaStem") hereby submits its Initial Pretrial Conference Brief.

A. LEGAL AND FACTUAL BACKGROUND

This case arises from the consolidation of six separate actions in five different states. Five of the actions were brought by PharmaStem and involve patent infringement claims against various medical providers and blood banks. The sixth action, brought by three of the defendants in PharmaStem's patent infringement actions, involves antitrust and state law tort claims relating to PharmaStem's attempts to enforce its patents.

PharmaStem is the holder of a number of patents, including U.S. Patents 6,461,645 B1 ("645 Patent") and 6,569,427 B1 ("427 Patent"), covering different aspects related to the collection, cryopreservation, and therapeutic use of hematopoietic stem cells found in umbilical cord blood. In July and August of 2004, PharmaStem filed suits

alleging infringement of the '645 and '427 patents against ViaCell, Inc. ("ViaCell") et al.,¹ CureSource, Inc., et al.,² Cord Blood Registry, Inc. ("CBR") et al.,³ Cryo-Cell International, Inc. ("CryoCell") et al.,⁴ and CorCell, Inc. ("CorCell") et al.⁵

On October 5, 2004, ViaCell filed a separate action against PharmaStem in the District Court of Delaware alleging violation of the antitrust laws, Lanham Act, and state laws relating to tortious interference and unfair and deceptive trade practices in enforcing the '645 and '427 patents ("Antitrust action"). Case No. 1:04-cv-01335-GMS, D.I. 1. CorCell and Cryo-Cell later joined in the suit. D.I. 11.

On October 29, 2004, the defendants in PharmaStem's patent infringement suits moved before the Judicial Panel on Multidistrict Litigation to consolidate the pretrial proceedings of the six separate actions before this Court, the District of Delaware. On February 17, 2005, the Judicial Panel issued a transfer order granting their motion.

¹ The other defendants named in this case were Obstetrical and Gynecological Associates, P.A. and Fempartners, Inc. Case No. 1:04-cv-11673-RWZ (D. Mass).

² The other defendants named in this action were Monica Aszlerbaum, Andrew Cassidenti, Eunice U. Lee, Carla Wells, Anita York, Eliot Romero, Kathy M. Anderson, Nasrin Farbakhsh, Bruce A. Hagadorn, Rajasree T. Seshadri, Arthur Goldstein, and Charles W. Moniak. PharmaStem has reached a settlement with CureSource, Eliot Romero, Kathy M. Anderson, and Charles Moniak. A default judgment has been entered against Nasrin Farbakhsh. Case No. 8:04-cv-00921-GLT-AN (C.D. Cal.).

³ The other defendant named in this case was Sutter Health, Inc. Case No. 3:04-cv-03072-JSW (N.D. Cal.).

⁴ The other defendant named in this case was Bruce Zafran, M.D. Case No. 8:04-cv-01740-JSM-TGW (M.D. Fl.).

⁵ The other defendants named in the case were Molly McBride, M.D. and Carlo M. Croce, M.D. Case No. 2:04-cv-03561-RK (E.D. Penn.).

B. PROCEDURAL STATUS OF THE TRANSFERRED CASES

1. PharmaStem v. ViaCell, Inc., Obstetrical and Gynecological Associates, P.A., and Fempartners, Inc. (Case No. 1:04-cv-11673-RWZ (D.Mass))

PharmaStem's complaint and the defendants' answers all have been filed. D.I. 37-39. The Massachusetts district court either denied or declared moot PharmaStem's various motions for temporary restraining orders and preliminary and permanent injunctions, enjoining ViaCell from taking further action in the Antitrust action. *Id.* When the case was transferred, there were no motions pending before the Massachusetts court.

2. PharmaStem v. CorCell, Inc., Molly McBride, M.D., and Carlo M. Croce, M.D. (Case No. 2:04-cv-03561-RK (E.D. Penn.))

PharmaStem filed its complaint (D.I. 1) and defendant CorCell filed its answer and counterclaims against PharmaStem, Nicholas Didier⁶ and Stembanc, Inc. D.I. 9. PharmaStem and counter-claimant Nicholas Didier moved to dismiss the counterclaims. D.I. 16, 33. When the case was transferred, these two motions were still pending before the Pennsylvania court. CorCell dismissed its counterclaims against Stembanc, Inc. D.I. 52.

Default was entered against defendants Molly McBride, M.D. and Carlo M. Croce, M.D. for failure to timely serve a responsive pleading. McBride and Croce moved to set aside the default, which the Pennsylvania court granted. D.I. 8, 19. McBride filed a motion to dismiss for lack of personal jurisdiction, which also was still pending when this case was transferred. D.I. 10.

⁶ Nicholas Didier is President and Chief Executive Officer of PharmaStem.

Defendants sought a stay of the proceedings pending a decision by the Judicial Panel on Multidistrict Litigation, which was granted. D.I. 55. At the time the transfer was granted, the Pennsylvania court had yet to rule on PharmaStem's motion for an injunction enjoining CorCell from taking further action in the Antitrust action. D.I. 26.

3. PharmaStem v. Cord Blood Registry, Inc. and Sutter Health, Inc. (Case No. 3:04-cv-03072-JSW (N.D. Cal.))

PharmaStem's complaint and defendants' answers and counterclaims against PharmaStem, Nicholas Didier, Archibald A. Grabinski⁷ and Stembanc, Inc. have been filed. D.I. 1, 9, 35. The Northern District of California denied counterclaim-defendant Nicholas Didier's motion to dismiss for lack of personal jurisdiction and granted counterclaim-defendant Archibald Grabinski's motion to dismiss for lack of personal jurisdiction. D.I. 109. PharmaStem's motion to dismiss CBR's counterclaims had not been ruled upon by the Northern District of California court at the time the case was transferred. D.I. 14, 18, 67. Furthermore, Nicholas Didier, Stembanc, and Archibald A. Grabinski's motions to dismiss CBR's counterclaims were still pending when the case was transferred. D.I. 25, 28, 32, 66, 68, 71. Similarly, Pharmastem's motion for a preliminary injunction against CBR to enjoin it from engaging in infringing activities also was pending. D.I. 99.

4. PharmaStem v. Cryo-Cell International, Inc., and Bruce Zafran, M.D. (Case No. 8:04-cv-01740-JSM-TGW (M.D. Fl))

PharmaStem's complaint and the defendants' answer and counterclaims have been filed. D.I. 1, 15. PharmaStem's motion to dismiss the counterclaims was pending before

⁷ Archibald Grabinski is President and Chief Executive Officer of Stembanc, Inc., a licensee of PharmaStem.

the Florida court when the case was transferred. D.I. 16, 20. The Florida court denied PharmaStem's emergency motion for a temporary restraining order enjoining Cryo-Cell from pursuing preliminary injunctive relief in the Antitrust action. D.I. 28.

PharmaStem's motion for a preliminary and permanent injunction, seeking to enjoin Cryo-Cell from taking further action in the Antitrust action, however, was pending when the case was transferred. D.I. 21.

5. PharmaStem v. CureSource, Inc., Monica Aszlerbaum, Andrew Cassidenti, Eunice U. Lee, Carla Wells, Anita York, Eliot Romero, Kathy Anderson, Nasrin Farbakhsh, Bruce A. Hagadorn, Rajasree T. Seshadri, Arthur Goldstein, and Charles W. Moniak (Case No. 8:04-cv-00921-GLT-AN (C.D. Cal.))

PharmaStem's complaint has been filed. D.I. 1. The defendants' answer and counterclaims have been filed, along with PharmaStem's reply to the counterclaims. D.I. 36, 41. The Central District of California court issued an order dismissing with prejudice defendants Eliot Romero, CureSource, Kathy M. Anderson, and Charles Moniak, as a result of the settlement they had reached with PharmaStem. D.I. 4, 17-19. Default judgment was entered against Nasrin Farbakhsh. D.I. 28. The Central District of California denied defendants' motion to stay proceedings pending a decision by the Judicial Panel on Multidistrict Litigation, but shortly thereafter the case was ordered transferred to this Court. D.I. 55. There were no motions pending before the Central District of California court when the case was transferred.

6. ViaCell, Inc., Cryo-Cell International, Inc., and CorCell, Inc. v. PharmaStem Therapeutics, Inc. (Case No. 1:04-cv-01335-GMS (D. Del))

ViaCell filed its complaint, and Cryo-Cell and CorCell join in ViaCell's complaint. D.I. 1, 11. PharmaStem filed its motion to dismiss the complaint. D.I. 28. The Delaware court denied PharmaStem's motion to dismiss. D.I. 61. ViaCell, Cryo-

Cell and CorCell filed a motion for entry of a preliminary injunction against PharmaStem, to which PharmaStem has responded. D.I. 4, 18, 22, 31, 32, 38. The Delaware court denied without prejudice the motion for a preliminary injunction. D.I. 61. There are no motions currently pending.

C. RELATED ACTIONS PENDING

In 2002, PharmaStem filed suit in the District of Delaware against ViaCell, Cryo-Cell, CorCell, and CBR, asserting infringement of U.S. Patents No. B1 5,004,681 ("'681 Patent") and U.S. Patent No. 5,192,553 ("'553 Patent"). (The '681 and '553 patents are distinct from the '645 and '427 patents involved in the instant action but, similarly, relate to the collection, cryopreservation, and therapeutic use of hematopoietic stem cells found in umbilical cord blood.) In October 2003, the jury found, by unanimous special verdict, that the '681 and '553 Patents were valid, enforceable, and willfully infringed by all four defendants. Post-trial motions for judgment as a matter of law and/or for a new trial were filed by the defendants, and this Court made the following post-trial rulings: (1) the Court set aside the jury verdict of infringement of both patents on different grounds, stating that the '553 Patent was not contributorily infringed as a matter of law and setting aside the jury's finding of infringement on the '681 Patent due to the jury's findings related to damages, and (2) upheld the jury verdict regarding the validity and enforceability of the '681 and '553 Patents.

In January 2005, PharmaStem filed a Notice of Appeal in the District of Delaware, which, together with the defendants' Notice of Appeal and Cross-Appeal, was docketed by the Federal Circuit in a consolidated case. The defendants filed a Notice of Jurisdictional Question requesting the Federal Circuit to dismiss PharmaStem's appeal for

lack of finality. On June 2, 2005, the Federal Circuit granted the defendants' Notice of Jurisdictional Question and dismissed PharmaStem's appeal and the defendants' cross-appeal.

On July 7, 2005, the District Court of Delaware entered final judgment in accord with the judgments it previously entered. In light of this order, PharmaStem filed a Motion to Reinstate the Appeal on July 13, 2005 and filed a Renewed Notice of Appeal with the District of Delaware on July 19, 2005, which is based on its previous appeal. The new appeal and the defendants' cross-appeal were docketed on July 26, 2005 (05-1490) and September 2, 2005 (05-0551) respectively. PharmaStem filed its initial appellate brief on September 16, 2005.

No other case known to counsel is pending in this or any other court that will directly affect or be directly affected by this Court's decision in the multidistrict litigation. If the appeals case is subsequently remanded for additional pretrial proceedings, the action may be considered as a potential tag-along action to the multidistrict litigation transferred to this Court.

D. ISSUES PHARMASTEM CURRENTLY VIEWS AS CRITICAL

PharmaStem is the owner of a pioneering invention that indisputably changed the world of hematopoietic stem cell transplantation by fundamentally adding to the universe of medical options for the treatment of many diseases and disorders. The inventors discovered that the blood in the umbilical cord and placenta of a newborn, formerly considered medical waste, contained stem cells that could be a valuable medical resource for persons in need of hematopoietic stem cell transplants. The pioneering work of the

PharmaStem inventors has since been well-publicized and their contribution is now roundly recognized by the scientific and medical communities.

PharmaStem has filed the above-referenced appeal from the orders entered by this Court on the '681 and '553 Patents, and multiple patent infringement actions on the related '645 and '427 Patents in various jurisdictions, where the pretrial proceedings have been consolidated and transferred to this Court. Despite proof of infringing activities by defendants ViaCell, CorCell, Cryo-Cell and CBR of the '681 and '553 Patents, and the fact that all of PharmaStem's patents relating to the collection, cryopreservation, storage and use of umbilical cord blood have only a couple of years to run, the defendants are permitted to continue their unlawful behavior. As the appeal and MDL pretrial proceedings progress, PharmaStem's patents move closer to their expiration.

As a result, PharmaStem is gravely concerned about the lack of enforcement of its valid patents against actual and potential infringers participating in the cord blood industry and that it is not being permitted to enjoy the full value of its invention. PharmaStem is continuously being harmed since its patents have very little time left to be enforced. PharmaStem has no way to recoup losses stemming from the loss of market share that the defendants obtain while infringing the patents during the appeal and the MDL. For example, PharmaStem currently has sixteen licensees who are in direct competition with defendant private cord blood banks, ViaCell, Cryo-Cell, CorCell and CBR, which form the royalty base for PharmaStem's income from its cord blood banking intellectual property. If the resolution of these patent infringement actions against the defendants in the appeal and MDL action does not occur soon, PharmaStem will lose market share and goodwill in the marketplace and will not be able to enforce its patent

rights in a timely manner. Allowing the defendants, especially the private cord blood bank defendants, to use their dominant positions in the private cord blood banking market to continue to grow their infringing businesses before this MDL is adjudicated -- or even delaying until time runs out on the patents altogether -- will cause PharmaStem irreparable harm and unjust hardship. PharmaStem's right to exclude granted by the patent would be diminished, and the express purpose of the Constitution, to promote the Progress of Science and the useful Arts (U.S. Const. Art. I, Sec. 8, Cl. 8), would be seriously undermined.

E. CLASS ACTION


There are no class action questions involved in this MDL.

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CERTIFICATE OF SERVICE

I do hereby certify that, on September 29, 2005, the within document was filed with the Clerk of Court using CM/ECF which will send notification of such filing to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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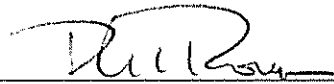
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